Federal Medical Device Regulations: What Are the Implications for Respiratory Care?

Reed M Gardner PhD

Introduction

The instrumentation used in respiratory care is among the most technologically advanced in medicine. Only advanced imaging techniques rival the technological changes that have occurred in the past decade in respiratory care. As a result, professionals involved in respiratory care have a responsibility to their patients and to themselves to use this new technology safely and effectively. Because there is a growing concern that medical technologies may be inappropriately used, there is an increasing need to make self-assessments of where we are and where the application of new technologies is leading us.

Because of concerns that manufacturers might produce inappropriate medical devices, in May 1976 the Congress of the United States enacted the Medical Device Amendment to the federal Food, Drug, and Cosmetic Act (PL 94-295).[1,2] The primary purpose of the amendment was to ensure that new medical devices were safe and effective. The law, administered by the Food and Drug Administration (FDA), has been controversial and severely criticized.[1]

By law, the definition of "medical device" is all-encompassing. Any item promoted for medical purposes that is not a "drug" is considered to be a medical device and is classified into one of three general categories:

Class I. General Control. Class I requires that manufacturers comply with "good manufacturing" practices. An example would be a bedpan.

Class II. Performance Standards. Class II devices must meet federally defined performance standards. An example would be a spirometer.

Class III. Life-sustaining or life-support devices. Class III devices are subject to the most extensive regulation. They cannot be marketed until the manufacturer demonstrates their safety and effectiveness to the FDA's satisfaction. An example would be a "closed-loop" computer-controlled ventilator.

Through classification panels, the FDA has identified more than 1,700 different devices, 50,000 products, and 7,000 manufacturers. Let's look into the current regulatory situation as it relates to respiratory care practitioners. Pulmonary function testing equipment and methodology have recently been standardized and will serve as a model to surmise what the effects of the Device Amendment on other devices might be.

Pulmonary Function Testing Standardization

In 1846, Hutchinson performed and published results from spirometry testing.[3] His spirometer was a water-filled device for the measurement of vital capacity and was very similar to spirometers used today. With his simple instrumentation, Hutchinson did some interesting experiments. For example, he monitored and recorded the deterioration of pulmonary function in a giant (7′ 3″) American man who was touring England with a circus, by measuring

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Dr Gardner is Professor of Medical Informatics, LDS Hospital—University of Utah, Salt Lake City, Utah.

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Reprints: Reed M Gardner PhD, LDS Hospital, 325 8th Avenue, Salt Lake City UT 84143.

his vital capacity repeatedly for several weeks preceding his death. Nearly a century later (1950), timed measurements were added to spirometry by Dr Edward A Gaensler at Boston University in cooperation with the Warren E Collins Company.[4,5] Gaensler's pioneering work led to the development of the forced vital capacity (FVC) maneuver and the measurement of the forced expired volume in the first second (FEV_1) and other time-related measures of dynamic pulmonary function. Since that time there have been a wide variety of devices developed for spirometry. These include the water-seal, rolling-seal, and bellows spirometers and Fleisch and wire-mesh resistor pneumotachometers. After the FVC had been in use for nearly 3 decades, the American Thoracic Society (ATS), in 1979, published recommendations for FVC spirometry.[6] In 1987, the ATS updated its spirometry recommendations.[7]

Based on the Medical Devices Amendment, which has been in place since 1976 and the spirometry standard that was published in 1979, the following 5 questions are posed:

1. Was there a need for standardization of spirometers in 1979? Yes. Based on the results of spirometer testing done in 1979, only 70% of the volume spirometers met ATS recommendations, and none of the flow devices performed acceptably.[8]

2. Has the state of the art of spirometer instrumentation improved since the development of standards? No. By 1987 the number of vendors of volume spirometers had dramatically increased and still only 70% of them were found to be acceptable.[9] In 1979, no flow-based spirometers were acceptable, whereas in 1987 about 30% were found to perform adequately.[8,9] Approximately 48% of the spirometers marketed today perform poorly![9]

3. Has the quality of data collected from pulmonary function laboratories improved to the point that standardization is no longer necessary? No. Based on results of FVC studies that I personally carried out at 28 different clinical laboratories in 1983, there is still need to improve the standardization of laboratory testing and quality control (Table 1).

Spirometry by 28 different laboratories found my FVC to be between 4.8 and 5.2 liters (5.0 ±4%). Variability of ±3% of FVC is typical of trained subjects.[6] Thus only 1/3 of the variability is attributed to poor test equipment and/or measurement technique. In the 4 years following publication of recommendations for instrumentation and test performance (1980-1983), this variability was judged acceptable.

On the other hand, the single breath diffusion capacity for the lung ($DLCO_{SB}$) measurement, which had not been standardized, showed a huge variability in both the predicted (±17%) and measured values (±21%). It appears from these preliminary findings that standardization of equipment and procedures can improve the quality of data collected. Recently the ATS has presented recommendations for standardization of the $DLCO_{SB}$ test,[10] pulmonary function testing equipment,[6,7,10] personnel,[11] quality assurance,[12] and the use of computers in the pulmonary function laboratory.[7,13]

4. How should pulmonary function devices be tested? The ATS has developed excellent performance-testing recommendations for spirometry,[6,7] which should be used. The questions of who does performance testing and how it is done are very important considerations. At the moment there are several possible places where such performance evaluations might be done.

The Emergency Care Research Institute (ECRI), a non-profit organization in the Philadelphia area, tests health devices and publishes results of evaluations. Health Devices is its monthly publication, available to hospitals and health care facilities.

Consumer Reports, a national publication, generally does not get into the details of evaluation deeply enough to satisfy scientific inquiry.

Scientific papers published in refereed journals are a likely source of current information on medical device performance.

Independent laboratories in the private sector have recently been recommended by the ATS as appropriate agencies to perform testing of spirometers. The precedent for such independent testing has already been established by Underwriters Laboratory (UL).

Table 1. Pulmonary Function Test Results, Range of Predicted and Measured Values on the Same Subject at 28 Different Clinical Laboratories.

Test	Predicted	Measured
FVC (L)	4.3 to 5.5	4.8 to 5.2
DLCO (ml/min/torr)	28.0 to 40.0	28.0 to 43.3

Government agencies have also tested and evaluated devices and systems.

Several years ago, Dr John L Hankinson of the National Institute of Occupational Safety and Health in Morgantown, West Virginia, developed a hydraulically driven syringe for testing spirometers. This spirometer testing device, which cost about $35,000, was used by my group in evaluating commercially available spirometers in the late 1970s.[8] More recently, Steven B Nelson at the University of Utah has developed a stepper-motor-controlled device costing only $7,000 that can be purchased by manufacturers and testing laboratories.

Methods for testing spirometers have recently been outlined by the ATS.[7] The 24 standardized testing waveforms proposed by the ATS consist of a variety of challenging, actual-patient spirograms, which cover situations that might occur in a wide variety of clinical situations, and specifically test the ability of spirometers to measure 'difficult' waveforms.

Testing of medical devices such as spirometers against standards is a sensitive issue, both from the legal and ethical viewpoints. Clearly, legal protection must be provided to the testing laboratory, and manufacturers need assurance that fair and accurate testing is done, without human prejudice. The criteria for testing must be explicitly stated, and the validation of testing devices must be made clear. At the moment, it appears that institutions such as ECRI, which have experience with the legal and ethical procedures involved in product testing, are probably the best agencies to test new medical devices. From the ethical standpoint, patients deserve to have accurate and reliable testing performed on them. It is a common belief of the scientific community that no data are better than bad data. Inaccurate measurements of vital data could lead physicians to make incorrect diagnostic and therapeutic decisions.

To give an example of how important the legal issues are, our spirometer testing project resulted in the filing of a $90 million lawsuit against the University of Utah, graduate student Steven B Nelson, and myself. Headlines in the April 3, 1987, Daily Utah Chronicle stated, "The University of Utah, a professor, and graduate student have been named defendants in a $90 million lawsuit filed in U.S. District Court." Clearly this type of action by a manufacturer has dampened my own personal interest in medical device testing and may dissuade others from getting into the medical device testing field.

5. What should be done by professional societies and the FDA to improve the quality of pulmonary function instrumentation and data? The Medical Devices Amendment of 1976 has not totally eliminated the manufacture and sale of inaccurate spirometers. In my opinion, these results are a sad commentary on the spirometry industry. The responsibility of providing accurate spirometers must be shared by both the manufacturer and the user. The ATS and the American Association for Respiratory Care (AARC) need to express their concern for the lack of adequate spirometer performance to manufacturers, and they need to work with them to improve the quality of available instrumentation.

Opportunities for Standards Development

The first 'warning shot' has been fired. Representatives of the U.S. government felt that industry and professional societies had not done the job well and thus gave authority to the FDA to police the industry. We, as professionals, must get more involved in setting standards for the industry—or others, less sensitive to our needs, will develop criteria that may cause discomfort to us all.[14]

The AARC has a unique opportunity to become involved in setting standards for two new and exciting groups of devices. The first involves setting up communication standards for ventilator and respiratory monitoring equipment. The second relates specifically to the use and validation of pulse oximeters.

Ventilator and Monitoring Communication Standards

Care of the acutely ill patient requires data from a wide variety of devices and instruments.[15–23] For example, it is not unusual for a patient in the ICU to be connected to a bedside cardiac monitor, a non-invasive blood pressure monitor, several infusion pumps, a ventilator, a pulse oximeter, and a urine-output measuring system. Each of these devices may be made by a different manufacturer, and each has

a different computerized communications interface. Currently, different manufacturers may use different algorithms or time constants to calculate derived indices (eg, compliance). Various manufacturers have also developed their own communications protocols and methods of formatting their data. For example, some manufacturers transmit data strings with headers, while others send only data strings. Although this may appear on the surface to be a trivial problem, it can be serious when one is trying to get two devices to communicate. A medical information bus (MIB) has been proposed to help solve this problem by providing a local area network around the patient that acquires data from all of the bedside devices.[16] Clinician-members of the AARC have not yet become involved in the development of these standards. The final details of the MIB and its computerized communications protocol are still under development. To make the network scheme work, development of industry-wide standards is essential. The Institute of Electrical and Electronic Engineers (IEEE) has a MIB committee (IEEE P1073) that is actively working in this area.

Manufacturers are not motivated to develop common communications standards. I believe that they would rather force us to use their equipment—thus eliminating their competition. What happens to us as users is that either (1) we pay a premium price for compatible devices that we are forced to buy from the primary manufacturer, (2) we do not get the monitoring or measuring device at all, or (3) we are not able to integrate the data from multiple devices conveniently.

There is a critical need to integrate data for patient care needs, quality control, staff management, and development of on-line charge-capture mechanisms.

The cost of acquiring data is high. We must become efficient as we care for the more acutely ill patient. We must document more and better ways to satisfy the quality-of-care and legal issues.

Most manufacturers have not yet caught the vision of the importance of integrating data from multiple sources. As members of the scientific medical community, we must educate our profession and the industry to the exciting opportunities that an integrated communications network would make available to us. We must also work harder at providing accurate and valid data from respiratory devices. Currently, too many false-positive alarms and too much 'noise' are being sent by bedside monitors to computerized data bases.[16,22,23]

The Pulse Oximeter: A Medical Device in Need of Standardization

The pulse oximeter is one of the most exciting and potentially valuable devices to enter the respiratory monitoring field in recent years.[24–28] The pulse oximeter is a device that provides clinically important data noninvasively in a timely fashion. By pulsing red and infrared light through the finger or ear and by using a detecting photodiode, the device measures oxygen saturation beat by beat. A self-contained display provides a continuous readout of data, or the device can communicate the data to a central computer data base. However, despite all its potential advantages, the pulse oximeter is a device in need of standardization.

There are currently more than 30 manufacturers of pulse oximeters. How does one know which device is satisfactory for clinical use? To determine the answer to this question, methods (standards) must be developed to determine:

1. How should the pulse oximeter be tested (bench vs clinical)?
2. What testing should be done?
3. Who should do the testing?
4. How and where should pulse oximeters be used?
5. How can one assure that the saturation data reported are accurate?

The AARC is in the best position of any group in this country to establish performance standards for pulse oximeters. I believe that if the AARC or other professional groups do not establish the standards, then manufacturers will continue to produce anything they can sell. As a consequence, the product supplied may not be in the best professional or patient interest. Although clinical use of data from pulse oximeters is widespread, careful clinical evaluation is still lacking. To address some issues of clinical requirements of monitoring, a group of anesthesiologists recently proposed standards for anesthesia monitoring.[29]

Conclusion

The establishment of standards by private professional groups is the best way to regulate the medical device industry. There is strong evidence that the FDA also agrees with this philosophy. In July 1986, the FDA offered a "cooperative agreement and availability of funds" to establish standards for Class II devices.[30] At the end of 1987, the development of an apnea-device standard by ECRI was the only project that had been funded. Recently, the FDA withdrew its requirements for development of a mandatory electrical safety standard because it felt that existing voluntary standards were being adhered to by manufacturers.[31] One of the primary voluntary standards in the electrical safety field was developed by the Association for the Advancement of Medical Instrumentation (AAMI). The FDA's recent publication of "FDA Policy for Regulation of Computer Products" is further evidence that the FDA is willing to back off from its strict mandatory performance standards if the industry will be responsive and responsible.[32]

Why then should the AARC be involved in the development of standards for the respiratory care industry? The AARC has the technical expertise to develop and set standards in this technologically complex field. The AARC can control its own destiny by establishing reasonable and prudent standards. If the AARC does not, others will. The AARC can assist manufacturers to better deliver quality products. Manufacturers do not have open access to the clinical scene and can learn much from health care professionals such as AARC members. With establishment of communications standards, we will be able to better—more efficiently, effectively, and accurately—transmit data from respiratory devices to computerized data bases.

How should the AARC become involved? There are several steps that can be taken by AARC leadership. First, in my opinion, the AARC should begin, through its Standards Committee or some other mechanism, by making recommendations on standardization of communications protocols and pulse oximetry. Second, the AARC should participate with existing standardization groups such as the Association for the Advancement of Medical Instrumentation (AAMI), American National Standards Institute (ANSI), National Committee for Clinical Laboratory Standards (NCCLS), Food and Drug Administration (FDA), American Society for Testing Materials (ASTM), and Institute of Electrical and Electronic Engineers (IEEE). Finally, the AARC should work with industry to validate standards with clinical trials and clinical demonstrations.

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